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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,709	11/05/2001	A. Gururaj Rao	0233C3	7017

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EXAMINER	
KUBELIK, ANNE R	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/010,709	RAO ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2004 and 18 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.02

DETAILED ACTION

1. Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 6,130,366 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The amendment filed 18 March 2005 proposes amendments to the claims that do not comply with 37 CFR 1.173(b), which sets forth the manner of making amendments in reissue applications. A supplemental paper correctly amending the reissue application is required.

Specifically, amendments must be shown relative to the issued patent (see 37 CFR 1.173 (g) and "allowed " is not a permitted indicator (see 37 CFR 1.173 (b)(2)).

A shortened statutory period for reply to this letter is set to expire ONE (1) MONTH or THIRTY (30) DAYS, whichever is longer, from the mailing date of this letter.

4. Applicant's response filed 17 September 2004 and 18 March 2005 make the same arguments; only the page numbers from the 18 March 2005 response are cited.

5. The amendments filed 5 November 2001 remain objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material that is not supported by the original disclosure is as follows:

The amendment of the paragraphs beginning at column 2, line 2, to column 3, line 26, constitutes new matter, as follows:

i. The deletion of SEQ ID NOs of the modified α-hordothionin proteins. Without the SEQ ID NOs:, it is not clear what substitutions were made. For example, column 2, lines 7-12 state that α-hordothionin has 5 lysines and 5 arginines and that a high lysine derivative was made. However, without recitation of the SEQ ID NO: of the derivative, one would not know that all the arginines were substituted. Similarly, it is not clear form column 2, lines 58-62, that the derivative made was a further derivative of SEQ ID NO:5 and not just a further derivative of SEQ ID NO:4. Lastly, one would not know the "other combinations of these substitutions" that make up derivates SEQ ID NOs:7 and 8 without recitation of the SEQ ID NOs:. This deletion of information constitutes new matter because the vagueness of the statements in the specification indicates that other possibilities may have been tried.

ii. Insertion of the phrases "however, substitution at position 12 did not work *in vivo*" and "however, substitution at position 10 did not work *in vivo*" in column 2, lines 52 and 67, respectively. The originally filed specification indicated that substitution at these positions would work. Column 2, lines 45-50, state "replacement of the cysteine at position 12 of thionin with lysine ... was found not to disrupt the 3-dimensional structure of the protein". Column 2, lines 58-62, state "by replacement of the serine residue at position 2 with aspartic acid, the

arginine at position 10 could be replaced with lysine". An earlier paragraph indicates that functional modeling data correlates with biological activity (column 2, lines 19-22); biological activity is in vivo activity. Thus, addition of the phrase indicated above is new matter.

The amendment of column 3, line 30, is not new matter, but merely corrects a typographical error, as do the other amendments to the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

The objection is repeated for the reasons of record as set forth in the Office action mailed 16 March 2004. Applicant's arguments filed 17 September 2004 and 18 March 2005 have been fully considered but they are not persuasive.

Applicant requests that the new matter be cancelled (18 March 2005 response pg).

This is not found persuasive because the MPEP §1453 states

> All amendments which include any deletions or additions must be made by submission of the entire text of each added or rewritten paragraph with markings (as defined above), except that an entire paragraph of specification text may be deleted by a statement deleting the paragraph without presentation of the text of the paragraph. Applicant must indicate the precise point where each amendment is made. All bracketing and underlining is made in comparison to the original patent, not in comparison to any prior amendment in the reissue application. Thus, all paragraphs which are newly added to the specification of the original patent must be submitted as completely underlined each time they are re-submitted in the reissue application

6. In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

7. Claims 1-21 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251. See 37 CFR 1.175. The nature of the defect is set forth above.

Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

> "Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

8. The rejection of claims 20-21 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of enhancing the lysine content of a plant, plant cell or seed transformed with a nucleic acid encoding the protein of claim 1, does not reasonably provide enablement for a method of enhancing the lysine content of any plant, plant cell or seed is withdrawn in light of Applicant's amendment of the claims.

Claim Objections

9. Claim 8 remains objected to because of the following informalities:

In claim 8, line 1 2, the comma after "7" should be deleted.

The objection is repeated for the reasons of record as set forth in the Office action mailed 16 March 2004. Applicant's arguments filed 17 September 2004 and 18 March 2005 have been fully considered but they are not persuasive.

Applicant urges that the claim has been amended (18 March 2005 response pg 9).

This is not found persuasive because the comma was not deleted.

Claim Rejections - 35 USC § 112

10. Claims 20-21 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards

as the invention. Dependent claims are included in all rejections. The rejection is modified from the rejection set forth in the Office action mailed 16 March 2004, as applied to claims 5-6, 15 and 20-21, due to applicant's amendment of the claims. Applicant's arguments filed 17 September 2004 and 18 March 2005 have been fully considered but they are not persuasive.

Claim 20 remains indefinite in its recitation of "causing a protein … to be expressed in tissues of the plant" and claim 21 remains indefinite in its recitation of "causing a protein … to be expressed in the cell or seed".

Applicant urges that the claim has been amended to include the step of transforming a plant cell (18 March 2005 response pg 11-12).

This is not found persuasive because it is unclear what the practitioner must do to cause the expression in a plant, plant cell or seed, as there is no inducible promoter in the expression cassette.

The following rejection is new, due to Applicant's amendment of the claims:

Claims 20-21 lack antecedent basis for the limitation "the expression cassette of claim 6" as claim 6 is drawn to a DNA sequence.

11. Claims 1-21 are free of the prior art, given the failure of the prior art to teach or suggest a protein of SEQ ID NO:1 with substitutions of lysine for one or more of the amino acids at positions 5, 11, 17, 19, 22, 30 and 41, and nucleic acids encoding those proteins.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866).217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne R. Kubelik, Ph.D.
July 5, 2005

ANNE KUBELIK, PH.D.
PRIMARY EXAMINER